

Material Information Spezial Lot 970

(according to EN ISO 9333)

Chemical Composition (Content in mass %):

Spezial Lot 970	Au	Ag	Pt	Zn	Ir
X = Content ≤ 0,1 mass %	68,0	23,5	4,4	4,05	X

This solder is free of Beryllium, Cadmium and Lead.

Manufacturer:

Kulzer GmbH

Bio-compatibility:

We certify that this product has been evaluated according to the internationally valid directives EN ISO 7405, "Dentistry – Evaluation of biocompatibility of medical devices used in dentistry" – and EN ISO 10993 series, "Biological evaluation of medical devices". The evaluation covers, among other things, possible risk of cytotoxicity, allergisation, irritation, and genotoxicity. The studies conducted were carried out in independent testing facilities according to OECD directives and fulfil the requirements of GLP (Good Laboratory Practice). The evaluation proves the biological compatibility of this dental solder.

Corrosion:

Corrosion testing was carried out at Kulzer's testing facility according to the EN ISO 9333 : "Dentistry – Hard solders", test of corrosion-resistance, test media: 0,1 molar lactic acid / common salt solution, 7 days at 37°C." The dental solder showed no signs of chemical corrosion.

Evaluation:

Based on the above test and evaluation, this solder is classified as biocompatible (biologically compatible) when used as intended. A clinical evaluation proved that specified characteristics and performance related requirements are fulfilled.

The conformity of Spezial Lot 970 with internationally valid directives is proven and certified by the Technical Control Board of Rheinland (CE 0197). This document is subject to an internal approval process. It was created electronically and is valid without signature.

Contact in Germany

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Giving a hand to oral health.



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